

SAS:sas 11/19/01 83249  
PATENT

Attorney Reference Number 5759-54451  
Application Number 09/522,278

No new matter is added. Reconsideration is respectfully requested.

Applicants thank Examiner Zara for the helpful telephone conference of November 15, 2001, wherein the amendment of claim 1 was discussed.

#### **Rejections under 35 U.S.C. §112, Second Paragraph**

Claim 1 was rejected as being indefinite in not providing antecedent basis for the phrase "the transport function of VP22." Claim 1 has been amended to recite "a transport function," thereby removing the rejection.

Claim 18 was rejected as being indefinite in not providing antecedent basis for the phrase "the VP22." Applicants submit that the amendment of claims 1 and 18 removes the rejection.

In view of the amendments of claims 1 and 18 reconsideration and withdrawal of the rejections are respectfully requested.

#### **Rejections under 35 U.S.C. §112, First Paragraph**

Claims 4, 9-12, 20, and 23 were rejected as allegedly the specification does not provided enablement for aggregated compositions with a polypeptide having a transport function. The Office action notes that the specification is enabling for aggregated compositions comprising the polypeptide of VP22 with a known transport function and an oligonucleotide. The Office action further notes that the specification is enabling for delivery of a polypeptide or peptide to target cells by linking the polypeptide or peptide to VP22 or a fragment of VP22 known to have transport function.

Applicants have amended claim 1 to clarify that the aggregated composition includes VP22 or a fragment of VP22 that has a transport function of VP22, and not any fragment of any polypeptide having any transport function. Claims 4, 9-12, 20 and 23 depend from claim 1, or a dependent claim thereof. Applicants submit that the amendment of claim 1 clarifies the nature of the polypeptide with transport function, namely that that polypeptide is VP22 or a fragment of VP22 with the transport function. As discussed above, the specification is enabling for these VP22 polypeptides. Thus, Applicants submit that the amendment of claim 1 removes this rejection. Reconsideration and withdrawal of the rejection of claims 4, 9-12, 20 and 23 is respectfully requested.

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### **Rejection under 35 U.S.C. §102**

Claims 1, 2, 5-8, 13-16, and 18-22 were rejected as allegedly being anticipated by Langel et al. (US. Patent No. 6,025,140, herein after the '140 patent).

As noted in the Office action, the '140 patent teaches the delivery of aggregated compositions to target cells. However, the '140 patent teaches the use of two specific peptides that increase the intracellular distribution of nucleic acid analogs, namely transportan and pAntennapedia (see column 5). The '140 patent further teaches specific fragments of transportan and pAntennapedia of use (see column 6). The '140 patent does not teach, nor suggest, the use of VP22, or fragments thereof. As such, the '140 patent does not anticipate, nor render obvious, amended claims 1 or 18, or claims that depend therefrom. Reconsideration and withdrawal of the rejection is respectfully requested.

### **Information Disclosure Statement**

Applicants thank Examiner Zara for initialing, signing and dating the PTO-1449 mailed February 14, 2001. However, Applicants note that the Examiner did not acknowledge receipt of Phelan et al. (Nature Biotechnology 16:440-3, 1998), which was submitted to the Patent and Trademark Office on February 14, 2001. Applicants respectfully request acknowledgement of receipt of the Phelan et al. reference. Alternatively, Applicants would be please to provide an additional copy of this reference upon the Examiner's request.

### **Priority Claim**

Applicants note that the previous Office action, dated September 11, 2000, acknowledged the priority claim, and requested certified copies of the priority documents. Applicants have now amended the specification to include the priority claim. Applicants are aware that certified copies of the priority documents still need to be provided to the U.S. Patent and Trademark Office, and will endeavor to expedite obtaining copies of the priority documents.

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### CONCLUSION

Applicants submit that claims 1-23 are now in condition for allowance. If any minor matters remain to be discussed before this application is allowed, the Examiner is invited to call the undersigned at the telephone number listed below.

Respectfully submitted,

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**Marked-up Version of Amended Claims and Specification**  
**Pursuant to 37 C.F.R. §§ 1.121(b)-(c)**

**In the specification:**

On page 1, after the title, insert the following paragraph:

**Priority Claim**

This application claims the benefit of United Kingdom Application No 9930499.0, filed December 24, 1999, and from United Kingdom Application No. 9905444.7, filed March 10, 1999.

**In the claims:**

1. (Amended) An aggregated composition comprising (a) a VP22 polypeptide or a fragment thereof having [the] a transport function of VP22, and (b) an oligonucleotide or polynucleotide.
2. (Reiterated) An aggregated composition according to claim 1, which further comprises a pharmaceutically acceptable excipient.
3. (Amended) An aggregated composition according to claim 1, wherein the [polypeptide is a] VP22 fragment [comprising] comprises amino acid residues 159-301 of VP22.
4. (Reiterated) An aggregated composition according to claim 1, wherein the oligonucleotide or polynucleotide comprises a circular plasmid.
5. (Reiterated) An aggregated composition according to claim 1, wherein the oligonucleotide or polynucleotide comprises modified phosphodiester linkages.
6. (Reiterated) An aggregated composition according to claim 5, wherein the modified phosphodiester linkages comprise phosphorothioate linkages.